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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,220	02/27/2004	James R. Zabrecky	8449-333-999	9733
20583	7590	02/23/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			TIDWELL, JUDY LILLE	
			ART UNIT	PAPER NUMBER

1642

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/789,220	<b>Applicant(s)</b> ZABRECKY ET AL.	
	<b>Examiner</b> Judy Lille Tidwell, PhD	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-70 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, 16, 17, 22, 23-30, 46-50, drawn to a complex comprising a heat shock protein, antigenic molecule, and a lectin, wherein said heat shock protein and/or antigenic molecule is/are glycosylated, and wherein the amount of lectin present in said complexes relative to the amount of heat shock protein is 1)  $\geq 40$  or 2)  $\leq 5$  ng lectin per mg heat shock protein and a kit comprising 1) a first container containing a composition comprising a population of noncovalent complexes, each complex comprising a glycosylated heat shock protein and antigenic molecule and 2) a second container containing purified lectin, classified in class 530, subclass 350.
- II. Claims 11-15, 18-21, drawn to a method of making a population of noncovalent complexes which comprise heat shock proteins, antigenic molecules, and lectins, wherein said heat shock proteins are glycosylated, classified in class 530, subclass 413.
- III. Claims 31-45, drawn to a method of treating a type of cancer comprising administering to a subject having cancer a therapeutically effective amount of a composition comprising a population of noncovalent complexes, each complex comprising a heat shock protein, an antigenic molecule, and a lectin, classified in class 424, subclass 193.1.
- IV. Claims 31-45, drawn to a method of treating a type of infectious disease comprising administering to a subject having an infectious disease a therapeutically effective amount of a composition comprising a population of noncovalent complexes, each complex comprising a heat shock protein, an antigenic molecule, and a lectin, classified in class 424, subclass 193.1.

- V. Claims 51-60, 68-69, drawn to complex comprising a lectin and a biologically active glycoprotein, wherein the amount of lectin present in said complexes relative to the amount of glycoprotein is 1)  $\geq 40$  or 2)  $\leq 5$  ng lectin per mg glycoprotein, classified in class 530, subclass 350.
- VI. Claims 61-67, 70, drawn to a method of delivering a therapeutic glycoprotein to a desirable site or a desirable cell type in a subject comprising administering a complex comprising a lectin and a biologically active glycoprotein and a pharmaceutically acceptable carrier, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are structurally and functionally distinct.

While the inventions of Groups I and V are polypeptides, in this instance the polypeptide of Group I is a complex of heat shock protein, antigenic molecule, and lectin, wherein said heat shock protein and antigenic molecule are glycosylated, whereas Group V is a complex comprising a lectin and a biologically active glycoprotein. Thus, the compositions of Groups I and V are structurally distinct molecules; any relationship between compositions of Groups I and V is dependent upon the correlation between the scope of the polypeptides that make up the complexes.

Inventions II-IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose that the methods of the different inventions would be used together. The method of making a population of noncovalent complexes which comprise heat shock proteins, antigenic molecules, and lectins, wherein said heat shock proteins are glycosylated (Group II), a method of treating a type of cancer (Group III), a method of treating a type of infectious disease (Group IV),

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and a method of delivering a therapeutic glycoprotein to a desirable site or a desirable cell type in a subject (Group VI) are all unrelated as they comprise distinct active steps and different effects which demonstrates that each method has a different mode of operation. Each invention performs a function using a structurally and functionally divergent material. For example, the method of making a complex where the heat shock protein and/or antigenic molecule are glycosylated in Group II would encompass an additional, distinct and different step than a method of treating a type of cancer in Group III or treating a type of infectious disease in Group IV or a method of delivering a therapeutic glycoprotein to a desirable site or a desirable cell type in Group VI.

Moreover, the methodology and materials necessary for whether the effect set forth in the preamble of each of the different inventions (i.e. treating cancer, treating an infectious disease, or delivering a therapeutic glycoprotein) differ significantly for each of the materials. Therefore, each method is divergent in materials and steps. For these reasons the inventions in Groups II-IV and VI are patentably distinct.

Inventions I and III, IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the complex comprising a heat shock protein, antigenic molecule, and a lectin (Group I) can be used in a materially different process than either Group III or IV.

Inventions V and VI are also related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the complex comprising a lectin and a biologically active glycoprotein (Group V) can be used in a materially different process other than delivering a therapeutic glycoprotein (Group VI) such as *in vitro* assays.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search of the literature required for one group is not required for another group, restriction for examination purposes as indicated is proper.

### ***Species Election***

This application contains claims directed to the following patentably distinct species of the claimed invention:

Groups I-VI contain 3 genres of patentably distinct species. The species that belong to genus 1 are the antigenic molecules all listed from page 54 to page 55. For example, tumor associated antigens (CA125), antigenic epitopes from viruses (HSV-1), epitopes from protozoa, and epitopes from parasites. The species that belong to genus 2 are the lectins, including a mannose binding lectin, Concanavalin A, or from Table 1 (see Specification, page 21). The species that belong to genus 3 are the relative amount of lectin present in said complex to the amount of heat shock protein or glycoprotein. The species include the following: greater than or equal to 40 ng lectin per mg hsp, 50-1000 ng lectin per mg hsp, 100-500 ng lectin per mg hsp, less than or equal to 5 ng lectin per mg hsp, 0.5-1 ng lectin per mg hsp, and 0.1-1 ng lectin per mg hsp.

Group VI contains an additional genus of patentably distinct diseases and disorders comprising cancer, an infectious disease, anemia, growth hormone deficiency disorder, enzyme deficiency disorder, or a condition of immune suppression.

If Applicant elects any of Groups I-V, then Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of the three genres, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, even if this requirement is traversed. If Applicant elects Group VI, then Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of the four genres, for prosecution on the merits to which the claims

shall be restricted if no generic claim is finally held to be allowable, even if this requirement is traversed.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the

rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Judy Lille Tidwell, PhD whose telephone number is 571-272-5952. The examiner can normally be reached on 8:00AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JLT

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**MISOOK YU**  
**PATENT EXAMINER**